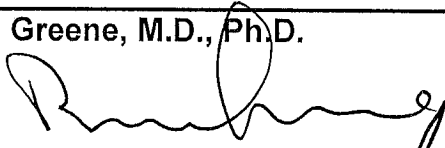
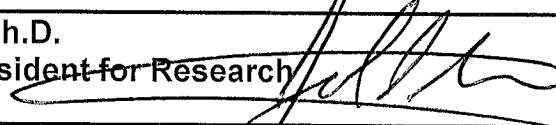


KESSLER FOUNDATION

Policies and Procedures Manual

SUBJECT: Research Misconduct	POLICY # 5026
APPROVED:	EFFECTIVE DATE:
Richard J. Greene, M.D., Ph.D. IRB Chair 	February 13, 2004
John DeLuca, Ph.D. Senior Vice President for Research 	REVISED DATE: <u>May 18, 2015</u>

PURPOSE

To establish policy and procedures for the Kessler Foundation and for any researchers who operate under the jurisdiction of the Kessler Foundation IRB in responding to allegations and apparent occurrences of misconduct in research conducted by or under the direction of any employee, student, volunteer or agent of Kessler Foundation in connection with his or her institutional responsibilities.

The objective of this policy is to ensure compliance with ethical standards in research; to promote understanding of the principles of scientific inquiry; to ensure the prompt and appropriate investigation of alleged or apparent misconduct; and to protect the rights of individuals, those who report misconduct, and those about whom allegations are made.

This policy is intended to implement the Federal Law 42 U.S.C. Section 289b and the regulations promulgated pursuant thereto, 42 CFR Part 50, Subpart A, 42 CFR Part 93, and 45 CFR Part 689.

APPLICABILITY

This policy applies to all Kessler Foundation employees and agents, staff members, trainees, students (including fellows), volunteers and physicians conducting research under the jurisdiction of the Kessler Foundation IRB. This includes personnel conducting research under the direction of an employee/agent of Kessler Foundation, and the use of property or facilities of Kessler Foundation in connection with scientific research.

ACCOUNTABILITY

Under the supervision of the President & CEO of Kessler Foundation (the "President"), the Senior Vice-President for Research of Kessler Foundation (the "Senior VP for Research") and such other persons as may be designated by the President, shall

ensure compliance with this policy. The President or persons designated by the President shall advise the administration of facilities at which Kessler Foundation research is conducted (including Kessler Institute for Rehabilitation and Children's Specialized Hospital) of this policy.

The Senior VP for Research will make an annual submission to the Office of Research Integrity (ORI) of the Office of the Secretary of HHS pursuant to 42 CFR Part 50.

DEFINITION

- A. **“Research misconduct”** –fabrication, falsification, plagiarism, committed in proposing, performing or reviewing research, or in reporting research results. Research misconduct does **not** include honest error, conflicting data, differences of opinion, or differences in interpretations or judgments about data or experimental design.
- Fabrication**-making up data or results and recording or reporting them.
Falsification- manipulating research materials, equipment or process, or changing or omitting data or results such that the research is not accurately represented in the research record.
Plagiarism-the appropriation of another person's ideas, processes, results or words without giving appropriate credit.
- B. **DHHS**- Department of Health and Human Services.
C. **PHS**- Public Health Service.
D. **ORI**- Office of Research Integrity.
E. **Complainant**- the individual, who made an allegation of research misconduct.
F. **Respondent**- the individual against whom the allegations was made.
G. **Good Faith**-as applied to complainant or witness, shall mean having a belief in the truth of one's allegation or testimony, which a reasonable person in the complainant's or witness's position would have, based on the information known to the complainant or witness at the time. An allegation is not in good faith or is made in bad faith if the complainant knew or had reason know it was false, or if the allegation as made with reckless disregard for or willful ignorance of information that would negate the allegation.
H. **Inquiry**- preliminary information gathering and preliminary fact finding.
I. **Preponderance of the evidence**- proof by information that, compared with that opposing it, leads to the conclusion that the fact at issue is more probably true than not.
J. **Investigation**- formal development of a factual record and examination of that record leading to a recommendation to make a finding of research misconduct, and which may include recommendations for other appropriate actions, including administrative actions.

POLICY

- A. Kessler Foundation staff members, trainees, students, volunteers and physicians and researchers, who operate under the jurisdiction of the Kessler Foundation IRB have an important responsibility to maintain high ethical standards in scientific

research conducted by Kessler Foundation personnel both on Kessler Foundation premises and in conjunction with other sites. These standards, based upon well-established principles of scientific research include validity, accuracy and honesty in proposing and performing research, in collecting, analyzing and reporting research results, and in reviewing the research of others. The failure to observe these principles may result in research misconduct and damages to Kessler Foundation and its image, the general public trust and the entire scientific community. Kessler Foundation personnel, who commit research misconduct, breach their obligations to Kessler Foundation.

B. Kessler Foundation shall make diligent efforts to assure that:

1. Those reporting alleged misconduct in good faith are protected from retaliation;
2. Appropriate action will be taken against individuals who attempt to retaliate against those reporting misconduct in good faith;
3. Appropriate action will be taken against individuals found to have made unsubstantiated allegations in bad faith (see Definition Section Item G); and
4. The reputations of those unfairly accused are not damaged or are restored.

C. Immediate Notification

All Kessler Foundation staff members, trainees, students, volunteers and physicians and researchers operating under the jurisdiction of the Kessler Foundation IRB also have the responsibility to report known or suspected instances of misconduct in research to the Senior VP for Research or a member of the Kessler Foundation IRB. The Senior VP for Research will convene an ad hoc committee to undertake a preliminary assessment, inquiry and investigation of any suspected instance of research misconduct.

During the course of the preliminary assessment, initial inquiry and investigation or otherwise, the following notifications shall immediately be made:

1. If the ad hoc Committee becomes aware of a risk to human subjects or deviations in an Institutional Review Board (IRB) approved protocol or other breach of Kessler Foundation policies regarding human subjects' research, the Chair of the Committee shall notify the Senior VP for Research and the IRB Chair.
2. If the Committee becomes aware of non-compliance with federal or state law or regulation or with Kessler Foundation policy, the Chair shall notify the Senior VP for Research.
3. If the Committee becomes aware of any facts that may affect current or potential federal or other funding for the respondent, or facts that the funding agency or sponsor needs to know to ensure appropriate use of federal or other funds and otherwise protect the public interest, the Chair shall notify the Senior VP for Research, who shall apprise the Office of Research Integrity (ORI), who will advise whether further notification of the pertinent funding agency or sponsor is required.
4. If there is found to be substantial evidence of any of the following, the Senior VP for Research shall be informed and shall immediately notify ORI (for research conducted under a Public Health Service grant or if the research results were

used in Public Health Service grant, fellowship or contract application), or other funding agency or sponsor as appropriate:

- a. There is an immediate health hazard to patients, human research subjects, laboratory workers or staff.
- b. There is an immediate need to protect federal or other funds or equipment.
- c. There is an immediate need to protect the human or animal subjects of the research.
- d. There is an immediate need to protect the interests of the person making the allegation or of the individual who is the subject of the allegation as well as his/her co-investigators and associates, if any.
- e. The alleged incident is expected to be publicly disclosed.
- f. There is an indication of possible criminal violations (notification of which must take place within 24 hours of discovery of same).

D. Ad hoc Committee to Conduct an Initial Inquiry into an Instance of Alleged Research Misconduct

The ad hoc Committee shall be established to conduct an initial inquiry into an allegation of misconduct in science.

1. Membership

The Committee shall be composed of:

- Two or more representatives of Kessler Foundation, as well as representatives from Kessler Institute for Rehabilitation Inc., and other facilities where Kessler Foundation research is conducted, as appropriate. The representatives shall be selected by the President upon recommendation from the Senior VP for Research.

2. The Committee chair shall be designated by the President of Kessler Foundation. The Chairperson or its designee shall call all meetings.

The functions of the Committee will be to:

- Conduct an initial inquiry, which shall involve information gathering and initial fact-finding to determine whether the allegation of misconduct or apparent instance of misconduct warrants further investigation. The Committee shall meet within seven (7) working days of the receipt of an allegation or report to begin the initial inquiry of the allegation by the Committee. The individual in question shall be notified in writing of the inquiry and shall be informed of his/her obligation to cooperate fully. The Committee shall, on behalf of Kessler Foundation, take custody for and secure the data and other material essential to the conduct of the initial inquiry and to potential future investigators after having determined which

data and materials are required. Efforts should be made to permit the research to continue while the initial inquiry and other procedures go forward;

3. Expenses of the Committee

Expenses related to the general functioning, administration and training of the Committee shall be borne by the operating budget of the research center of the Kessler Foundation.

E. Initial Inquiry

The initial inquiry shall involve information gathering and initial fact finding to determine whether an allegation of misconduct in science or apparent instance of misconduct warrants further investigation.

1. Preliminary assessment of allegation

The Committee shall perform a preliminary assessment of the allegation or report to determine if an initial inquiry is warranted. This determination shall be limited to whether the allegation meets the definition of misconduct in research as set forth in the Definition Section Item A, and whether there is or could be adequate information available to proceed with an initial inquiry. This determination shall take place within ten (10) working days of the Committee's receipt of the allegation or report. When an initial inquiry is not felt to be warranted, the Committee's reasons shall be documented and the complainant shall be informed. The identification of the respondent shall be kept confidential from everyone without a need to know.

2. Initiation of initial inquiry

The Committee shall begin the initial inquiry within ten (10) working days of its determination that the allegation warrants an initial inquiry.

3. Conflict of Interest/Bias

It is the responsibility of each member of the Committee to divulge potential conflicts of interest. In the event that any member of the Committee has any real or apparent personal or professional conflicts of interest or bias with respect to the respondent, complainant or case, that member shall be excused. Such conflicts include, but are not limited to, involvement with the research in question, competition with the respondent or a previous or ongoing close professional or academic relationship with either respondent or complainant.

4. Notification of Initial Inquiry

Within twenty-one (21) calendar days of the initiation of the initial inquiry, the respondent, the complainant, the President, Senior VP for Research and IRB

Chair shall be notified in writing of the inquiry by the Chairperson of the Committee. Under certain circumstances set forth in Policy Item C., the Office of Research Integrity (ORI) in the case of research conducted under a PHS grant or another pertinent funding agency must be immediately notified.

5. Rights and obligations of the Respondent

The respondent shall be informed of the charges, of the opportunity to be heard, as well as the obligation to cooperate fully and that unreasonable refusal to supply relevant material or other uncooperative behavior shall constitute violation of this policy.

6. The Committee may sequester research data and other materials relevant to the inquiry.

7. Duration of Initial Inquiry

The Committee shall complete the inquiry and prepare a written report summarizing the conduct of the initial inquiry and its conclusions for the Senior VP for Research within sixty (60) calendar days from the date the initial inquiry began. Should circumstances warrant, the Committee may request an extension of time from the Senior VP for Research. Documentation of the reasons for exceeding the 60 day period shall be recorded and the respondent shall be notified.

8. Decision of initial inquiry made by Committee

The Committee shall decide by majority opinion whether the initial inquiry reveals:

- a. Finding of No Cause, i.e., insufficient credible evidence of misconduct in science to warrant further investigation. The reasons for this decision shall be documented in sufficient detail to permit later assessments of this decision if necessary. A written report summarizing the conduct of the initial inquiry and its conclusions shall be prepared for the Senior VP for Research. The respondent shall be given a copy of the report, and the respondent's comments, if any, shall be made part of the record. The complainant and the President/CEO shall be notified in writing of the Committee's decision. The Committee may also make recommendations to the Senior VP for Research regarding actions to restore the reputation of the respondent, and may consult with the respondent in this regard. The Committee may also make recommendations to the Senior VP for Research concerning actions against a complainant found to have made unsubstantiated allegations in bad faith (see Definition Section Item G.).
- b. Finding of Cause, i.e., of the existence of credible evidence of misconduct in science sufficient to warrant further investigation. In this event, the Initial Inquiry Committee shall recommend to the Senior VP for Research that an

investigation be initiated to formally examine and evaluate all relevant facts to determine if misconduct has occurred.

A written report summarizing the conduct of the initial inquiry and its conclusions shall be prepared for the Senior VP for Research. The respondent shall be given a copy of the report, and the respondent's comments, if any, shall be made part of the record. Comments of the respondent about the Committee's decision must be filed with the Committee within five (5) working days of receipt of the report. The complainant, the respondent and the President/CEO shall be notified in writing of the Committee's decision.

If the Committee finds there is a high probability that false or misleading information has been or may be disseminated to the scientific community and that such dissemination could cause significant harm, the Committee may recommend that the Senior VP for Research (if an investigation is initiated) inform the following individuals of the existence and status of the investigation: (1) editors of scientific journals in which articles or other publications concerning the research under investigation have been published or are pending publication; and (2) program directors of scientific meetings at which the research under investigation is scheduled to be presented.

9. Decision and Actions of the President

The President has the sole discretion to accept, reject or modify the recommendations of the Committee. The Senior VP for Research shall make a decision concerning the recommendations of the Committee within ten (10) working days of receipt of the Committee's report.

- a. If the Senior VP for Research accepts the recommendation of the Committee that there is insufficient credible evidence of misconduct in science to warrant further investigation, the case shall be closed.

The Senior VP for Research shall notify in writing the respondent, the complainant, all individuals interviewed or otherwise informed of the allegation, and the President of the disposition of the allegation. In the event that the ORI or another pertinent funding agency or sponsor was notified during the initial inquiry, under the circumstances enumerated in Immediate Notification Policy Item C., the same shall be informed by the Senior VP for Research of the finding of no cause following the inquiry and that Kessler Foundation considers the case closed. When necessary and in consultation with the respondent, diligent efforts shall be undertaken fully to restore the reputation of the respondent.

If the Senior VP for Research finds that the allegation was made in bad faith (see Definition Section Item G), pursuant to a recommendation of the Committee, he/she shall determine whether and what administrative actions should be taken against the complainant pursuant to applicable Kessler Foundation policies, procedures or contracts.

All research records, original data and other original materials sequestered by the Committee from the respondent or furnished by others shall be returned.

The Chairperson of the Committee shall gather the original records of the proceedings of the initial inquiry and copies of all documents and other materials furnished to the Committee. This file shall be sent to the Senior VP for Research, who shall seal it and retain it in a locked confidential cabinet or storage for at least six (6) years and preferably indefinitely. The documents shall, upon request, be provided to authorized personnel representing the funding agency or sponsor. Otherwise, access to materials in the file shall be available only upon authorization of the Senior VP for Research or the President for exceptional cause.

- b. If the Senior VP for Research accepts the recommendation of the Committee that there is credible evidence of misconduct in science sufficient to warrant further investigation, the Senior VP for Research shall initiate a formal investigation. All files accumulated by the Committee in this matter shall be transferred to the Office of the Senior VP for Research.

The Senior VP for Research shall provide notice of the investigation in writing to the respondent, the complainant, the President/CEO and the Director of the Office of Research Integrity (ORI) if the research in question was funded by the Public Health Service or if the research results were used in a Public Health Service grant, fellowship or contract application, or the director of another pertinent funding agency or sponsor if required (see paragraph below). Notification should include the name of the respondent, the nature of the charges, and the specific applications or grant numbers involved. The Senior VP for Research may also decide to notify certain editors of journals or program directors of scientific meeting pursuant to a recommendation from the Initial Inquiry Committee.

Under certain circumstances set forth in Policy Item C., the funding agency must be immediately notified.

- c. If the Senior VP for Research for good reason cannot accept the recommendation of the Committee, the Senior VP for Research shall document his or her reasons and communicate these in writing to the Committee, the respondent, the complainant, and the President. In consultation with the Senior VP for Research, the President of Kessler Foundation will decide which procedure outlined in Section 9.a or Section 9.b. shall be followed. The President's decision shall be communicated in writing to the Director of ORI.

10. Expenses of the Initial Inquiry

Expenses of initial inquiries shall be borne by the operating budget of the research center of the Kessler Foundation.

F. Investigation

The investigation shall be a formal examination and evaluation of all relevant facts to determine if misconduct in science has occurred. It shall include interviewing the complainant and the respondent as well as others, who might have relevant information; talking with experts; considering materials and/or comments submitted by the respondent and complainant; reviewing relevant literature, publications, correspondence, memos, etc.

1. Formation of an ad hoc Committee on Conduct of Research

An investigative panel ("Ad hoc Committee on Conduct of Research") shall be appointed by the Senior VP for Research, consisting of three scientists with strong research experience and other appropriate qualifications to judge the issues raised in the investigation. These individuals may be internal or external to Kessler Foundation. Members of the original ad hoc Committee conducting the initial inquiry may not be appointed to the ad hoc Committee on Conduct of Research.

2. Conflict of Interest/Bias

In making appointments to the ad hoc Committee on Conduct of Research, precautions shall be taken against real or apparent personal or professional conflicts of interest or bias with respect to the respondent, complainant or the case. For example, ad hoc Committee members should not be involved with the research in question, should not be professional competitors with the respondent, and should not have a previous or ongoing close professional or academic relationship with either respondent or complainant.

3. Rights and obligations of Respondent

The respondent shall be notified of the charges, the opportunity to be heard, and the obligation to cooperate fully with the investigation. Such notice shall inform the respondent that the investigation may determine: (a) whether or not misconduct has occurred; and/or (b) if the actions or conduct investigated are/is otherwise unacceptable within the Kessler Foundation for proposing, performing or reviewing research or reporting research results. The respondent shall also be informed that unreasonable refusal to supply relevant material or other uncooperative behavior constitutes violation of this policy.

4. Objections to proposed Ad hoc Committee on Conduct of Research members

The Respondent and the complainant shall be informed of the proposed membership of the ad hoc Committee on Conduct of Research. If the respondent or the complainant objects to the participation of any member of the ad hoc Committee on Conduct of Research based upon personal or professional conflict of interest or bias with respect to the respondent, complainant or the case, this objection must be made within five (5) working days in writing to the Senior VP for Research, who shall decide whether to replace the challenged member. The decision of the Senior VP for Research shall be final. Such challenges to the membership of the ad hoc Committee on Conduct

of Research must be resolved prior to the official appointment of the members by the Senior VP for Research.

5. Appointment of and charge to the Ad Hoc Committee on Conduct of Research

The Senior VP for Research shall appoint the members of the ad hoc Committee on Conduct of Research and shall administer the charge to the Committee. The official date of the initiation of the investigation shall be the date of the first meeting of the ad hoc Committee on Conduct of Research. This shall be within thirty (30) calendar days of the completion of the initial inquiry (transmission of the written report to the Senior VP for Research by the Committee performing the initial inquiry).

6. Chairperson of the Ad Hoc Committee on Conduct of Research

A chairperson may be appointed by the Senior VP for Research or the ad hoc Committee on Conduct of Research may be asked to choose its chairperson at its first meeting.

7. Staff to the Ad Hoc Committee on Conduct of Research

The Senior VP for Research shall assign staff to assist the ad hoc Committee on Conduct of Research. Staff members shall hold their activities for the Committee in strict confidence.

8. Protection of complainant from retaliation

The Senior VP for Research shall coordinate efforts to protect the complainant from retaliation during and after the inquiry and investigation, working with all relevant Kessler Foundation offices in these efforts.

9. Conduct of Investigation

a. Procedural Protection

Every effort shall be made to ensure a comprehensive, fair and expeditious investigation. The respondent shall have the opportunity to examine all evidence forwarded to the Subcommittee, to be represented by legal counsel, to present evidence to the ad hoc Committee on Conduct of Research, including witnesses on the respondent's behalf, and to cross-examine witnesses, including the complainant. Anonymous third-party statements are not admissible as evidence.

b. Confidentiality

The respondent and the complainant shall be afforded confidential treatment to the extent possible and permitted by law. Files shall be kept in a central location in a locked cabinet accessible only to the appropriate individuals taking part in the investigation.

c. Testimony before the Ad Hoc Committee on Conduct of Research

If feasible, tape recordings shall be made of all testimony given. Documentation (including original data) substantiating the ad hoc Committee on Conduct of Research findings will be carefully prepared, secured, and maintained. When available, transcriptions of the taped interviews shall be provided to the persons interviewed for comment or revision and included as part of the investigative file.

d. Sequestering of additional data and material

The ad hoc Committee on Conduct of Research may secure and sequester additional pertinent original research data, records, documents and other material from the respondent or others, using inventories and signed receipts for all material taken. If additional original materials are required for the proceedings, the Committee chairperson or designee shall give the respondent copies of original documents and records and reasonable access to original or materials, which cannot be duplicated during the proceedings. Materials sequestered shall be stored in a manner to ensure their preservation.

e. Consultants and Assistance for the Ad Hoc Committee on Conduct of Research

The ad hoc Committee on Conduct of Research may seek additional expert scientific advice and/or the advice of students or postdoctoral fellows as appropriate to the status of the respondent.

f. Broadening or change in subject matter of investigation

If during the investigation, information becomes available, which the ad hoc Committee considers substantially related to the original charge from the Senior VP for Research, the Committee may broaden the scope of its charge and give written notice to the respondent of the new scope. If the Committee does not consider the new information substantially related to the original charge, the Committee may refer the new information to the Senior VP for Research as the basis of a new allegation.

10. Decision of Ad Hoc Committee on Conduct of Research

In reaching a conclusion on whether there was misconduct in science, the burden of proof is on Kessler Foundation to support its case by a preponderance of the evidence.

Decisions made by the ad hoc Committee on Conduct of Research shall be based on a majority vote. There may be a minority report. The results of any vote taken shall be made know to the Senior VP for Research in the written report of the ad hoc Committee on Conduct of Research.

11. Duration of Investigation

The investigation shall be completed within ninety (90) calendar days of its initiation date to allow sufficient time for review of the report by the complainant, respondent and the Senior VP for Research and the President, and submission of the report, including the decision of President, to the funding agency, within a total of one hundred and twenty (120) calendar days of the initiation of the investigation. If the investigation cannot be completed within these time limits, Kessler Foundation may request an extension of time from the ORI (in the case of research conducted under a PHS grant or if the research results were used in a PHS grant, fellowship or contract application) or from another pertinent funding agency or sponsor if required. If such an extension is granted, the respondent shall be so notified.

12. Report of the Ad Hoc Committee on Conduct of Research

Upon conclusion of its investigation, the ad hoc Committee on Conduct of Research shall prepare a written report for the Senior VP for Research. A copy of the report shall be given to the respondent, the IRB Chairman and the Director of the Office of Research Integrity (ORI). The complainant may be provided with those portions of the report that address his/her role and opinions in the investigation. Comments, if any, must be filed with the ad hoc Committee on Conduct of Research within ten (10) working days for receipt of the report. These comments shall be made part of the report and considered by the Senior VP for Research.

13. Action Taken on the Report and Decision of the Ad Hoc Committee on Conduct of Research

The Senior VP for Research shall present the report and decision of the Committee to the President of Kessler Foundation. The President, in consultation with the Senior VP for Research, will determine what actions shall be taken in response to the Committee's report and decision.